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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,775	12/08/2000	Hans A. Mische		2947

28534 7590 09/30/2008  
MIRICK, O'CONNELL, DEMALLIE & LOUGEE, LLP  
1700 WEST PARK DRIVE  
WESTBOROUGH, MA 01581

EXAMINER
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PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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09/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/733,775	<b>Applicant(s)</b> MISCHE, HANS A.	
	<b>Examiner</b> NIHIR PATEL	<b>Art Unit</b> 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08.06.2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-26 is/are pending in the application.
- 4a) Of the above claim(s) 3-8, 11, 14, 15 and 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 9, 10, 16, 17, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 6<sup>th</sup>, 2008 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed on August 6<sup>th</sup>, 2008 have been fully considered but they are not persuasive. The applicant argues that Beyar's balloon is not removable from the bone once it is filled with solidifying fluid. The examiner would like to point that the applicant has not claimed that the balloon is removable from the bone. The applicant claims that the means of expanding the device are removed from the bone. In Beyar's reference means of expanding the device is defined as the inflation tube 88 and inflation the inflation tube 88 is removed from the bone (see figures 7A-7D and col. 28 lines 1-10).

### ***Response to Amendment***

3. The examiner acknowledges the amendment filed on August 6<sup>th</sup>, 2008. The amendment comprises amending claims 1, 2, 9, 10, 16, 17; withdrawing claims 3-8, 11, 14, 15, 18-24; cancelling claims 12, 13 and adding claims 25 and 26.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims **1, 2, 9, 16 and 17** are rejected under 35 U.S.C. 102(e) as being anticipated by Beyar et al. (US 6,127,597).

6. **As to claim 1**, Beyar teaches an apparatus that comprises a delivery catheter **80 (see figure 7A-7D; see column 26 lines 65-67 and column 27 lines 1-10)** an expandable device **82** for occupying space within bones releasably carried by the delivery catheter (**see column 27 lines 60-67 and column 28 lines 10-25**); and a means for expanding the device **88 (see column 27 lines 50-60)** configured for removal from the bone upon expansion of the expandable device (**see response to arguments above**); whereby the expanded device mechanically is configured to fixate the fracture (**see column 27 lines 60-67**) once the delivery catheter and the means of expanding the device are removed from the expandable bone (**see response to arguments above**).

7. **As to claim 2**, Beyar teaches an apparatus wherein the means of expanding the device is an inflatable catheter (**see column 28 lines 1-10**).

8. **As to claim 9**, Beyar teaches an apparatus wherein the expanded device joins separated bone segment (**see figures 7A-7D**).

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9. **As to claim 16**, Beyar teaches an apparatus that comprises an expandable tubular device **82**, a delivery device comprising a balloon **88 (the inflation tube is defined as the balloon)**; the expanding tubular device removably attached to the balloon **(see figures 7A-7D)**; whereby the balloon expands the tubular device at the treatment site, whereby the balloon is configured to be removed leaving the expanded tubular device in place to span bone segments **(see figures 7A-7D)**.

10. **As to claim 17**, Beyar teaches an apparatus wherein the expandable tubular device comprises a tubular mesh **(see figures 7A-7D)**.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims **10, 25 and 26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Beyar et al. (US 6,127,597).

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13. **As to claims 10, 25 and 26**, Beyar substantially discloses method steps comprising utilizing an expandable device **82 (see figures 7A-7D; column 27 lines 10-20)** for occupying space within a bone segment **(see figures 7A-7D)**; creating an access hole **45** in bone **(see figures 7A-7D)**; disposing the structure upon a delivery device; inserting the structure within the bone segment **(see figures 7A-7D)**; advancing the structure to the desired location within the bone segment **(see figures 7A-7D)**; activating a portion of the delivery device in order to cause expansion of the structure **(see figures 7A-7D)**.

The claimed method steps would have been obvious because they would have resulted from the use of the device of Beyar.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/  
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772